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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,940	01/12/2000	LUDWIG WILDT	990667/RSB	7875

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/403,940

Applicant(s)

WILDT ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Amendment and response filed on 06/10/03 are acknowledged. Claims 18-29 are pending in the Application. Claims 18-22 and 29 are elected with traverse. Claims 23-28 are withdrawn from consideration as drawn to the non-elected invention.
2. In response to the Applicants' arguments regarding restriction requirements the examiner emphasizes that the pending claims 18-29 grouped in Groups I and II corresponding to the method and apparatus claims lack the unity of invention, since their common technical feature, i.e. an end expiratory gas from an animal or a human and a signal obtained from this gas, is well known in the art, see all references cited below, and therefore is not a special technical feature, which makes the restriction proper and FINAL.

### ***Specification***

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

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Extensive mechanical and design details of apparatus should not be given.

4. The amended abstract of the disclosure is objected to because it does not properly reflect the subject matter disclosed in the specification, excluding the claims. Nowhere does the specification disclose “generating a signal according to the comparing of values in step (d)”, which is unclear and indefinite step of the method. Correction is required. See MPEP § 608.01(b).

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18-21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites in step (d) “comparing values from step (c) with a table of values” and in step (e) “generating a signal according to the comparing of values in step (d)”. It is not clear, what “values” are meant here – are these values from the same patient taken at previous times, are these standard values, are these predetermined values? No “table of values” is disclosed in the specification, and therefore this definition is vague. Step (e) is completely unclear. What is meant by “generating a signal according to the comparing of values”? What signal? How can it be generated from comparison of two values? It is difficult for anyone of ordinary skill in the art to interpret this step in a sensible meaning for practicing the invention. Moreover, no such step is disclosed in the specification, which renders the claim unclear and indefinite, as well as lacking antecedent basis.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 18-20 and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Casparie et al. (US 5,069,220)

Casparie teach a method for monitoring lung functioning by measuring an end exhaled CO<sub>2</sub> in a certain volume by NDIR spectroscopy (col. 6, lines 1-6), comparing the value obtained with the predetermined value, e.g. of CO<sub>2</sub> in inhaled breath, and generating an alarm signal if the value falls beyond the predetermined limits. He discloses “precise control over the sampling period to assure the extraction of samples only during the end tidal region, without relying on the sensing of relatively large respiratory gas flows (col. 2, lines 1-6).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 21 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Voll, Casparie in view of the prior art cited by the Applicants (PA) or Savadi et al. (Ind. J. Medic. Research).

Casparie does not teach applying his method of monitoring CO<sub>2</sub> in exhale breathe for predicting ovulation.

PA or Savadi disclose a correlation between the CO<sub>2</sub> content in exhale breathe and ovulation, which makes it obvious for anyone of ordinary skill in the art to apply the method of Casparie for predicting ovulation because of the clear correlation between this physiological process and CO<sub>2</sub> content, demonstrated by PA and Savadi.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Weinfurt et al. (US 3,811,040)* disclose an algorithm for representing physiological parameters, including pO<sub>2</sub> and pCO<sub>2</sub> and their deviation from normal predetermined parameters; *Neumann et al. (US 4,356,475)*, *Raemer (4,648,396)*, *Wong (US 4,928,703)*, *Culver et al. (US 5,45,160)* teach a method for monitoring lung functioning by measuring exhaled CO<sub>2</sub> in a certain volume by IR spectroscopy, comparing the value obtained with the predetermined value, e.g. of CO<sub>2</sub> in inhaled breath, and generating an alarm signal if the value falls beyond the predetermined limits; *Howard (US 5,060,656)* teaches "a method for analyzing a metabolic rate by producing proportional sample of the expired gas", including CO<sub>2</sub>, and measuring "CO<sub>2</sub> content in the expired gas from the rate of pressure decay in the test chamber, conducting a volumetric analysis of the proportional sample to determine total volume of expired gas, and then correlating O<sub>2</sub> content, CO<sub>2</sub> content and total volume of expired gas to provide a measure of the metabolic rate of the subject being studied" (Abstract). The method comprises comparing the values obtained with the previous results with the signal generated, which reflects the changes (see Fig. 14-16).

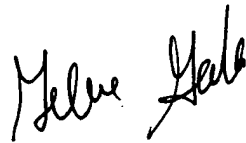
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh

A handwritten signature in black ink, appearing to read 'Yelena Gakh', written in a cursive style.

9/4/03